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L1 and asthma	2

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DB=USPT,PGPB,JPAB,EPAB,DWPI; PLUR=YES; OP=ADJ

<u>L3</u>	L1 and asthma	2	<u>L3</u>
<u>L2</u>	L1 and ashtma	0	<u>L2</u>
<u>L1</u>	immunoferon or inmunoferon or glycophosphopept\$5	8	<u>L1</u>

END OF SEARCH HISTORY

(FILE 'HOME' ENTERED AT 12:56:49 ON 11 APR 2003)

FILE 'CAPLUS, MEDLINE, USPATFULL, EUROPATFULL, PATOSWO' ENTERED AT  
12:57:01 ON 11 APR 2003

FILE 'REGISTRY' ENTERED AT 12:57:25 ON 11 APR 2003  
E "IMMUNOFERON"/CN 25

L1 1 S E3

FILE 'CAPLUS, MEDLINE, USPATFULL, EUROPATFULL, PATOSWO' ENTERED AT  
12:59:01 ON 11 APR 2003

L2 2 S L1

FILE 'CAPLUS, MEDLINE, USPATFULL, EUROPATFULL, PATOSWO' ENTERED AT  
13:01:15 ON 11 APR 2003

L3 68 S IMMUNOFERON OR INMUNOFERON OR GLYCOPHOSHOPEP?

L4 3 S L3 AND (ASTHMA OR ALLEGY OR INFLUENZA)

L1 ANSWER 1 OF 1 REGISTRY COPYRIGHT 2003 ACS  
RN 365212-33-5 REGISTRY  
CN **Immunoferon (9CI)** (CA INDEX NAME)  
ENTE Oral immunomodulator; active principle is a glycoconjugate consisting of  
Ricinus communis protein and Candida utilis polysaccharide  
MF Unspecified  
CI MAN  
SR CA  
LC STN Files: BIOSIS, CA, CAPLUS, TOXCENTER

\*\*\* STRUCTURE DIAGRAM IS NOT AVAILABLE \*\*\*  
2 REFERENCES IN FILE CA (1962 TO DATE)  
2 REFERENCES IN FILE CAPLUS (1962 TO DATE)

4 ANSWER 1 OF 3 CAPLUS COPYRIGHT 2003 ACS  
 ACCESSION NUMBER: 2000:627968 CAPLUS  
 DOCUMENT NUMBER: 133:202992  
 TITLE: **Glycophosphopeptical** or Nigella sativa seeds  
 for **asthma/allergy** therapy that targets  
 T-lymphocytes and/or eosinophils  
 INVENTOR(S): Nassief, Nida Abdul-Ghani  
 PATENT ASSIGNEE(S): Al-Jassim, Rawaa, Australia; Al-Kaisi, Ban; James,  
 David  
 SOURCE: PCT Int. Appl., 28 pp.  
 DOCUMENT TYPE: Patent  
 LANGUAGE: English  
 FAMILY ACC. NUM. COUNT: 1  
 PATENT INFORMATION:

PATENT NO.	KIND	DATE	APPLICATION NO.	DATE
WO 2000051580	A2	20000908	WO 2000-IB222	20000302
WO 2000051580	A3	20011018		
W: AE, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CR, CU, CZ, DE, DK, DM, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, US, UZ, VN, YU, ZA, ZW, AM, AZ, BY, KG, KZ, MD, RU, TJ, TM RW: GH, GM, KE, LS, MW, SD, SL, SZ, TZ, UG, ZW, AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE, BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG				
GB 2348132	A1	20000927	GB 2000-5003	20000301
EP 1242102	A2	20020925	EP 2000-909548	20000302
R: AT, BE, CH, DE, DK, ES, FR, GB, GR, IT, LI, LU, NL, SE, MC, PT, IE, FI, CY				
US 2002061841	A1	20020523	US 2001-944564	20010904
PRIORITY APPLN. INFO.:			GB 1999-4777	A 19990302
			GB 1999-13341	A 19990608
			WO 2000-IB222	W 20000302

TI **Glycophosphopeptical** or Nigella sativa seeds for **asthma**  
 /allergy therapy that targets T-lymphocytes and/or eosinophils  
 AB A pharmaceutical compn. for the treatment and/or prophylaxis of diseases  
 caused by type I hypersensitivity reactions consisting essentially of  
**glycophosphopeptical**, or pure Nigella Sativa seeds, in a concn.  
 which stimulate Th1 lymphocytes and selectively switch-off the  
 eosinophilic airway inflammation. A method of treatment of allergy using  
 Th1 stimulating agents, to be administered to a mammal such as human in  
 need of such treatment in a shot of 5 days only, resulted in significant  
 decrease in symptom score started day 3, and in sputum eosinophils by day  
 14, followed by long-term clin. remission of a mean of 6 mo. The BCG-like  
 Th1 stimulation is also used in treating diseases in which the body  
 defensive mechanism is a cell-mediated immunity, including viral  
 infections, including **influenza** and common cold, chronic and  
 recurrent urinary tract infection, pelvic inflammatory diseases as  
 neuroimmune appendicitis, cancer, Crohn's disease and facial palsy.  
 ST **glycophosphopeptical** immunostimulant cell mediated immunity;  
 allergy T cell eosinophil **glycophosphopeptical** immunostimulant;  
**asthma** T cell eosinophil **glycophosphopeptical**  
 immunostimulant  
 IT Intestine, disease  
 (Crohn's; **glycophosphopeptical** or Nigella sativa seeds for  
**asthma/allergy** therapy targeting t-lymphocytes and/or  
 eosinophils)  
 IT Immunoglobulins  
 RL: BPR (Biological process); BSU (Biological study, unclassified); BIOL  
 (Biological study); PROC (Process)

(E, type 1 IgE-mediated hypersensitivity; **glycophosphopeptical** or *Nigella sativa* seeds for **asthma**/allergy therapy targeting t-lymphocytes and/or eosinophils)

IT Lymphocyte  
(activation; **glycophosphopeptical** or *Nigella sativa* seeds for **asthma**/allergy therapy targeting t-lymphocytes and/or eosinophils)

IT Reproductive tract  
(adnexitis; **glycophosphopeptical** or *Nigella sativa* seeds for **asthma**/allergy therapy targeting t-lymphocytes and/or eosinophils)

IT Eye, disease  
(allergic conjunctivitis; **glycophosphopeptical** or *Nigella sativa* seeds for **asthma**/allergy therapy targeting t-lymphocytes and/or eosinophils)

IT Nose  
(allergic rhinitis; **glycophosphopeptical** or *Nigella sativa* seeds for **asthma**/allergy therapy targeting t-lymphocytes and/or eosinophils)

IT Dermatitis  
(atopic; **glycophosphopeptical** or *Nigella sativa* seeds for **asthma**/allergy therapy targeting t-lymphocytes and/or eosinophils)

IT Drug delivery systems  
(capsules; **glycophosphopeptical** or *Nigella sativa* seeds for **asthma**/allergy therapy targeting t-lymphocytes and/or eosinophils)

IT Immunity  
(cell-mediated; **glycophosphopeptical** or *Nigella sativa* seeds for **asthma**/allergy therapy targeting t-lymphocytes and/or eosinophils)

IT Urticaria  
(chronic; **glycophosphopeptical** or *Nigella sativa* seeds for **asthma**/allergy therapy targeting t-lymphocytes and/or eosinophils)

IT Allergy  
**Asthma**  
(diagnosis; **glycophosphopeptical** or *Nigella sativa* seeds for **asthma**/allergy therapy targeting t-lymphocytes and/or eosinophils)

IT Larynx  
(edema; **glycophosphopeptical** or *Nigella sativa* seeds for **asthma**/allergy therapy targeting t-lymphocytes and/or eosinophils)

IT Cytokines  
RL: BAC (Biological activity or effector, except adverse); BSU (Biological study, unclassified); BIOL (Biological study)  
(eosinophil chemotactic factor; **glycophosphopeptical** or *Nigella sativa* seeds for **asthma**/allergy therapy targeting t-lymphocytes and/or eosinophils)

IT Paralysis  
(facial palsy; **glycophosphopeptical** or *Nigella sativa* seeds for **asthma**/allergy therapy targeting t-lymphocytes and/or eosinophils)

IT Drugs  
(gastrointestinal; **glycophosphopeptical** or *Nigella sativa* seeds for **asthma**/allergy therapy targeting t-lymphocytes and/or eosinophils)

IT Allergy inhibitors  
Anti-inflammatory agents  
Antiasthmatics  
Antitumor agents  
Antiviral agents  
Common cold

Drug delivery systems  
Eosinophil  
Immunostimulants  
Influenza  
Mycobacterium BCG  
(**glycophosphopeptical** or *Nigella sativa* seeds for  
**asthma/allergy therapy targeting t-lymphocytes and/or**  
**eosinophils**)

IT Interferons  
RL: BAC (Biological activity or effector, except adverse); BOC (Biological occurrence); BSU (Biological study, unclassified); BIOL (Biological study); OCCU (Occurrence)  
(**glycophosphopeptical** or *Nigella sativa* seeds for  
**asthma/allergy therapy targeting t-lymphocytes and/or**  
**eosinophils**)

IT T cell (lymphocyte)  
(helper cell/inducer, TH1; **glycophosphopeptical** or *Nigella sativa* seeds for **asthma/allergy therapy targeting t-lymphocytes and/or eosinophils**)

IT Allergy  
(immediate hypersensitivity; **glycophosphopeptical** or *Nigella sativa* seeds for **asthma/allergy therapy targeting t-lymphocytes and/or eosinophils**)

IT Respiratory tract

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Urinary tract  
(infection; **glycophosphopeptical** or *Nigella sativa* seeds for **asthma/allergy therapy targeting t-lymphocytes and/or eosinophils**)

IT Respiratory tract  
(inflammation; **glycophosphopeptical** or *Nigella sativa* seeds for **asthma/allergy therapy targeting t-lymphocytes and/or eosinophils**)

IT Drug delivery systems  
(lozenges; **glycophosphopeptical** or *Nigella sativa* seeds for **asthma/allergy therapy targeting t-lymphocytes and/or eosinophils**)

IT Cell activation  
Cell proliferation  
(lymphocyte; **glycophosphopeptical** or *Nigella sativa* seeds for **asthma/allergy therapy targeting t-lymphocytes and/or eosinophils**)

IT Appendix  
(neuroimmune appendicitis; **glycophosphopeptical** or *Nigella sativa* seeds for **asthma/allergy therapy targeting t-lymphocytes and/or eosinophils**)

IT Drug delivery systems  
(ointments, creams; **glycophosphopeptical** or *Nigella sativa* seeds for **asthma/allergy therapy targeting t-lymphocytes and/or eosinophils**)

IT Drug delivery systems  
(ointments; **glycophosphopeptical** or *Nigella sativa* seeds for **asthma/allergy therapy targeting t-lymphocytes and/or eosinophils**)

IT Drug delivery systems  
(powders; **glycophosphopeptical** or *Nigella sativa* seeds for **asthma/allergy therapy targeting t-lymphocytes and/or eosinophils**)

IT Lymphocyte  
(proliferation; **glycophosphopeptical** or *Nigella sativa* seeds for **asthma/allergy therapy targeting t-lymphocytes and/or eosinophils**)

IT Tuberculin  
RL: BSU (Biological study, unclassified); BIOL (Biological study)  
(purified protein deriv.; **glycophosphopeptical** or *Nigella*

IT sativa seeds for **asthma/allergy therapy targeting t-lymphocytes and/or eosinophils**)

IT Nose (rhinitis, perennial; **glycophosphopeptical** or *Nigella sativa* seeds for **asthma/allergy therapy targeting t-lymphocytes and/or eosinophils**)

IT *Nigella sativa* (seeds; **glycophosphopeptical** or *Nigella sativa* seeds for **asthma/allergy therapy targeting t-lymphocytes and/or eosinophils**)

IT Drug delivery systems (solns., nasal; **glycophosphopeptical** or *Nigella sativa* seeds for **asthma/allergy therapy targeting t-lymphocytes and/or eosinophils**)

IT Drug delivery systems (solns., ophthalmic; **glycophosphopeptical** or *Nigella sativa* seeds for **asthma/allergy therapy targeting t-lymphocytes and/or eosinophils**)

IT Drug delivery systems (suspensions; **glycophosphopeptical** or *Nigella sativa* seeds for **asthma/allergy therapy targeting t-lymphocytes and/or eosinophils**)

IT Drug delivery systems (syrups; **glycophosphopeptical** or *Nigella sativa* seeds for **asthma/allergy therapy targeting t-lymphocytes and/or eosinophils**)

IT Drug delivery systems (tablets; **glycophosphopeptical** or *Nigella sativa* seeds for **asthma/allergy therapy targeting t-lymphocytes and/or eosinophils**)

IT Drug delivery systems (topical; **glycophosphopeptical** or *Nigella sativa* seeds for **asthma/allergy therapy targeting t-lymphocytes and/or eosinophils**)

IT Drug delivery systems (vaginal; **glycophosphopeptical** or *Nigella sativa* seeds for **asthma/allergy therapy targeting t-lymphocytes and/or eosinophils**)

IT 87139-86-4, **Inmunoferon**  
RL: BAC (Biological activity or effector, except adverse); BSU (Biological study, unclassified); THU (Therapeutic use); BIOL (Biological study); USES (Uses) (**glycophosphopeptical** or *Nigella sativa* seeds for **asthma/allergy therapy targeting t-lymphocytes and/or eosinophils**)

L4 ANSWER 2 OF 3 MEDLINE  
ACCESSION NUMBER: 92377675 MEDLINE  
DOCUMENT NUMBER: 92377675 PubMed ID: 1509986  
TITLE: [Immunologic clinical evaluation of a biological response modifier, AM3, in the treatment of childhood infectious respiratory pathology].  
Valoracion clinica inmunologica de un modificador de la respuesta biologica, AM3, en el tratamiento de la patologia respiratoria infecciosa infantil.  
AUTHOR: Sanchez Palacios A; Garcia Marrero J A; Schamann F  
CORPORATE SOURCE: Servicio de Alergologia, Hospital Insular, Las Palmas.  
SOURCE: ALLERGOLOGIA ET IMMUNOPATHOLOGIA, (1992 Jan-Feb) 20 (1) 35-9.  
PUB. COUNTRY: Journal code: 0370073. ISSN: 0301-0546.  
DOCUMENT TYPE: Spain  
(CLINICAL TRIAL)  
(CONTROLLED CLINICAL TRIAL)  
Journal; Article; (JOURNAL ARTICLE)

LANGUAGE: Spanish  
FILE SEGMENT: Priority Journals  
ENTRY MONTH: 199209  
ENTRY DATE: Entered STN: 19921009  
Last Updated on STN: 19980206  
Entered Medline: 19920918

AB To assess the immunoclinical effectiveness of a biological response immunomodulator, we used AM3 (**glycophosphopeptide**), a glucomannan polysaccharide extracted from the cell wall of a strain of *Candida utilis*, in 20 children with asthmatic. . . . the intradermal reaction of 5 antigens (*Trichophyton*, *Candida albicans*, tuberculin, *E. coli* and bacterial antigens). In the treated group, the **immunoferon** (AM3) reduced the symptoms, the intensity and frequency of the bronchospasm, and the symptomatic medication (table I, II and III)... . . behaved like an immunostimulant, improving the clinical situation and progress in patients with infectious respiratory disorders. We consider that the **immunoferon** constitutes a coadjuvant therapy to bacterial immunotherapy.

CT Check Tags: Human  
Antibiotics: TU, therapeutic use  
Antitussive Agents: TU, therapeutic use  
Asthma: CO, complications  
Asthma: TH, therapy  
\*Biological Response Modifiers: TU, therapeutic use  
Bronchial Spasm: CO, complications  
Bronchial Spasm: TH, therapy  
\*Calcium Phosphates: TU, . . .

RN 87139-86-4 (**Immunoferon**)

L4 ANSWER 3 OF 3 USPATFULL  
ACCESSION NUMBER: 2002:119853 USPATFULL  
TITLE: **Asthma/allergy therapy that targets**  
T-lymphocytes and/or eosinophils  
INVENTOR(S): Nassief, Nida Abdul-Ghani, Doha, IRAQ

	NUMBER	KIND	DATE
PATENT INFORMATION:	US 2002061841	A1	20020523
APPLICATION INFO.:	US 2001-944564	A1	20010904 (9)

	NUMBER	DATE
PRIORITY INFORMATION:	GB 1999-4777	19990302
DOCUMENT TYPE:	Utility	
FILE SEGMENT:	APPLICATION	
LEGAL REPRESENTATIVE:	AL-JASSIM, Rawaa, 2578 River Woods Drive, Naperville, IL, 60565	
NUMBER OF CLAIMS:	24	
EXEMPLARY CLAIM:	1	
LINE COUNT:	772	

CAS INDEXING IS AVAILABLE FOR THIS PATENT.

TI **Asthma/allergy therapy that targets T-lymphocytes and/or eosinophils**  
AB . . . diseases in which the body defensive mechanism is a Cell Mediated Immunity, including viral infections, as but not limited to **influenza** and common cold, Chronic and recurrent urinary tract infection, pelvic inflammatory diseases as neuroimmune appendicitis, cancer, crohns disease and facial. . .  
SUMM . . . generally directed to the fields of medicine and pharmacology, and specifically directed to a pharmaceutical composition for the treatment of **asthma/allergy**, consisting essentially of Glycophosphopeptical, or as an equivalent pure *Nigella sativa* seeds, which is active to stimulate T-helper lymphocytes type 1 therefor selectively switching-off the eosinophilic inflammation, also treating

viral respiratory tract infections (flue & **influenza**), other viral infection, urinary tract infection, pelvic inflammatory diseases in particular neuroimmune appendicitis, cancer, crohns disease and facial palsy.

SUMM [0003] **Asthma** is the epidemic of the new millennium. Despite the increase in our knowledge, the morbidity, mortality and prevalence of **asthma** and other allergic diseases are increasing as shown by WHO statistics. (1)

SUMM [0004] Barnes J December 1999, review the current state of anti-**asthma** therapy, over the past 10 years there have been striking improvement in the treatment of **asthma** largely as a result of the earlier and more widespread use of inhaled corticosteroids. The developments of new treatments for **asthma** has proved difficult, although several immunologic approaches are undergoing preclinical and clinical assessment. Antileukotrienes are the only new class of drugs to treat **asthma** that have been introduced in the past 25 years, but their efficacy is somewhat limited and unpredictable, as compared with. . . .

SUMM . . . . was not associated with large reductions in markers of eosinophilic inflammation, bronchovascular permeability, or mucus hypersecretion. Alternative therapies for corticosteroid-dependant **asthma**, such as methotrexate, cyclosporine and oral gold, are problematic and have high incidence of adverse effect. (2)

SUMM . . . . accordingly an outstanding need for an effective and convenient means for treating and/or preventing type I IgE-mediated hypersensitivity reactions, including **asthma**, in mammals.

SUMM [0008] **Glycophosphopeptical**: The present inventor has, surprisingly, found that a short-term administration of **Glycophosphopeptical** (Glicofopeptical) to patients suffering from **asthma** is capable of treating and/or preventing **asthma**, **Glycophospeptical** is marketed under the trade names "IMMUNOFERON" and "INMUNOFERON" drug by Industrial Farmaceutica Cantabria, S.A. (Spain), **Glycophospeptical** is a GLUCOMANNAN from Candida utilis to be used as an immunostimulant. . . . and stimulating cell mediated immunity. It is not indicated for the treatment of diseases caused by type I hypersensitivity and **asthma** defined

SUMM . . . . of natural killer cells was reversed to near their levels in young healthy adults. These observations help to explain how **glycophosphopeptical** aids in the restoration of natural cellular immunity and its possible application as an adjuvant to bacterial & viral vaccines. . . .

SUMM [0010] **Inmunoferon** enhances the activities of early-type interferon inducers and natural killer cells, although it is not an interferon inducer by itself.. . . .

SUMM [0019] The following studies are considered relevant to the relation between *N. sativa* and **asthma** Sayed 1980: The oil is used in the treatment of **asthma**, respiratory oppression and coughs. The active principal, nigellone, has been isolated from the volatile oil fraction and is reported to be useful in the treatment of bronchial **asthma**. (9)

SUMM . . . . immunity to tuberculosis by stimulating Cell Mediated Immunity mediated by T lymphocytes (Th1). The relation of BCG vaccination to **asthma** is a debate. BCG has also been used as a therapeutic agent in the treatment of cancer, inducing Cell Mediated. . . .

SUMM [0031] **Asthma** is an inflammatory mediator soup. (21)

SUMM . . . . of selectively switch-off the eosinophilic airway inflammation, normalizing serum interferon This can be achieved by using a novel class of **asthma** therapy, which is the subject of this invention. "days" therapy with a BCG-like Th1 stimulation .fwdarw. long term clinical remission

SUMM [0037] The present invention is introducing a new class of anti-allergy/anti-**asthma** therapy that target the pre-inflammatory phase of the allergic reaction being defined by the

SUMM present inventor as "Th1 lymphocytes" and. . . .  
[0038] This present invention provides a pharmaceutical composition and treatment of **asthma/allergy**, consisting essentially of **Glycophosphopeptical**, or an equivalent pure *Nigella sativa* seeds, which is active to stimulate T-helper lymphocytes type I therefor selectively switching-off the. . . .

SUMM [0039] The present inventor has, surprisingly, provided a method of treatment for patients suffering from **asthma/allergy**, administering **Glycophosphopeptical** to a mammal such as human in need of such treatment a shot of 5 days only, to get a, . . . .

SUMM . . . . for the treatment and/or prophylaxis of diseases caused by type I IgE-mediated hypersensitivity reaction, such as extrinsic, intrinsic or mixed **asthma**, allergic and perennial rhinitis, allergic conjunctivitis, chronic urticaria, atopic dermatitis, and/or laryngeal oedema, to be administered to a mammal such. . . .

SUMM [0043] The present invention is specifically directed to a medicament characterized in that said Th1 stimulating agent comprises **Glycophosphopeptical** in free base form, or a pharmaceutically acceptable salt or hydrate, or any pharmacologically active form.

SUMM [0046] The use of Th1 stimulating agents in the treatment of allergy/ **asthma** is dependent on the fact that interferon is an *in vivo* Eosinophilic Chemotactic Factor, and that serum interferon and Th1. . . .

SUMM [0047] The method of treating a chronic **asthma** and allergy using 5 days schedule is based on that the recommended dose of Th1 lymphocytes stimulating agent is sufficient. . . .

SUMM . . . . a body immune defensive mechanism is Cell Mediated Immunity as viral respiratory tract infections such as, but not limited to **influenza** and common cold, other viral infections.

SUMM . . . . Additionally the present invention provide a method of treatment of viral respiratory tract infections such as, but not limited to **influenza** and common cold, other viral infections comprising the administration to a mammal such as a human in need of such. . . .

SUMM . . . . preferably 5 days for type 1 hypersensitivity reaction, of particular interest but not limited to the chronic corticosteroid-dependent allergy and **asthma**. It provides a steroid saving activity.

SUMM [0057] Manufacturing a pharmaceutical preparation to provide a therapy for mammals including humans for the treatment of **asthma** and allergy, also a Th1 stimulating and Cell Mediated Immunity stimulating remedy for viral diseases urinary tract infection, pelvic inflammatory disease, crohns disease, and facial palsy. Containing the active ingredient **Glycophosphopeptical** or the pure seeds of *Nigella sativa* as an equivalent. May be administered orally as capsules, tablets, slow release preparations, . . . .

DETD . . . . invention was conceived during October 1993, after an experiment of nature that happened to the inventor. Being sever asthmatic her **asthma** was relieved after certain health incident. As an immunologist she linked the incident with interferon. This is considered as Stage. . . . I. Stage II: The discovery that interferon is a potent *in vivo* Eosinophil Chemotactic Factor. Stage III: A marketed drug **immunoferon (glycophosphopeptical)**, indicated for diseases unrelated to type 1 hypersensitivity, was linked with allergy in a novel way (depending on the above). . . .

DETD . . . . and severity of the allergic condition after an informed consent into the study. Group 1 including 60 patients treated with **immunoferon** Group 2 including 60 patients treated with placebo.

DETD [0060] 1 - Diseases involved include seasonal allergic rhinitis, allergic conjunctivitis, chronic urticaria, **asthma**, and laryngeal edema.

DETD . . . . the total dose received and the schedule of therapy were verified to find the best method of treating various allergies. **Glycophosphopeptical** was given in addition to the conventional

DETD therapy. The full course of 15 g total dose, was divided over 5. . . [0062] Alternatively a single dose of 500 mg **glycophosphopeptical**, Single dose of 1000 mg **glycophosphopeptical**, or one day therapy. Any of this treatment can be repeated on need.

DETD [0076] **Asthma**: dyspnoea, wheeze, and cough.

DETD [0078] During the course of **Glycophosphopeptical** treatment, 80% of the treated patients showed a significant decrease in symptom score in the treated group compared to placebo. . . by day 3, reaching maximum in day 7. Such symptomatic improvement is totally unexpected particularly in patients with allergic rhinitis, **asthma** and laryngeal edema.

DETD [0079] Above all, is the observation that a long-term effect for this short-term therapy was noticeable! During **glycophosphopeptical** treatment it was possible to stop all other forms of therapy, including steroids. Hence the present invention is useful as a treatment and/or prevention of allergy and **asthma**.

DETD [0080] Side effects: few are mentioned in the manufacturer's leaflet, **glycophosphopeptical** is not contraindicated for **asthma** or allergy, no other side effects were noticed during this short course of therapy.

DETD [0081] Stage IV: Nine patients age range 36-72 with chronic severe **asthma** of a duration ranging between 1-32 years, all of whom were on a maximal dose of broncodilators (as recommended by maintenance corticosteroids, were chosen on account of poor response to conventional treatment, were treated according to the present invention administering **glycophosphopeptical** orally as in the following design of study:

DETD [0083] Day 1: is the beginning of **glycophosphopeptical** treatment, 1000 mg **glycophosphopeptical** is administered to the patient 8 hourly, for 5 days (total of 15 grams or 30 capsule) over the whole. . .

DETD [0092] Was carried out to assess "the alteration in airway flow and bronchial patency resulting from **glycophosphopeptical** treatment" by measuring changes in FEVI, PEFR, FEF25% (alveolar), FEF50% (small airways), FEF75% (large airways).

DETD [0094] Hypersecretion of heavy mucus or sputum, resulting in mucus-related symptoms, is characteristic of **asthma**. The eosinophil levels in the sputum are generally found to correlate with the severity of the disease. The sputum produced by the patients during the course of **glycophosphopeptical** therapy was consequently observed for changes both at a macroscopic and a microscopic level

DETD [0101] The total number of asthmatic patients treated with **glycophosphopeptical** is: 25 patients in stage III+10 patients in stage IV+20 patients during the year 1999.

DETD [0104] The reduction in symptom score as a result of **glycophosphopeptica** therapy is shown in table 1

TABLE 1

Mean symptom score	<b>Glycophosphopeptical</b> (N = 55)	Placebo (N = 35)
Day 0	34.5	33.2
Day 3	20.5	27.3
Day 7	9.66	29.7
Day 14	5.8. . .	
DETD	[0109] There was a decrease in the percentage of sputum eosinophils with <b>glycophosphopeptical</b> therapy from 80% to less than 10% within the first two weeks of <b>glycophosphopeptical</b> therapy. In addition the use of student t test shows significant decrease in the number of sputum eosinophils after <b>glycophosphopeptical</b> therapy as compared to pre-treatment number.	

DETD [0111] After the end of the course of **glycophosphopeptical** therapy, during which a total of 30 capsules of **glycophosphopeptical** were administered to each subject, no further **glycophosphopeptical** was administered. Over the next 23 months, the subjects' symptoms were regularly assessed on the following criteria:

DETD [0115] Need for traditional forms of **asthma** therapy . . . mild, being manifested only in some shortness of breath, with mild coughing and small amounts of sputum. Traditional forms of **asthma** therapy were required only when the subjects were suffering from colds. At least eight out of the ten subjects were. . . for each subject during the long-term follow up period was on average reduced from several times per month (prior to **glycophosphopeptical** therapy) to 1-3 times per year.

DETD [0119] Conclusion: **Glycophosphopeptical** is an agent that can be used in treating **asthma** of all types and severity, allergic/ perennial rhinitis, and other allergies. This short-term therapy produce Long-term effect

DETD . . . Stage V: is the discovery that *Nigella sativa* (also known as fitch, black cumin, or love-in-the-mist) is an equivalent to **glycophosphopeptical**. The use of the pure seeds of *Nigella sativa* for the preparation of an **asthma** and allergy agent in a concentration which was found to perform substantially the same function in substantially the same way to obtain substantially the same results as with **glycophosphopeptical**.

DETD [0125] In addition *Nigella sativa* and **glycophosphopeptical** are useful in the treatment of facial palsy, possibly because facial palsy is possibly a complication of a viral infection.

CLM What is claimed is:

1. Use of **glycophosphopeptical** for the treatment and/or prophylaxis of allergy/**asthma** for administration to a mammal such as a human in need of such treatment.
2. Use of **glycophosphopeptical** for the preparation of an **asthma**/allergy drug 7 such as extrinsic, intrinsic or mixed **asthma**, allergic and perennial rhinitis, allergic conjunctivitis, chronic urticaria, atopic dermatitis, and/or laryngeal oedema, to be administered to a mammal such. . .
3. A Pharmaceutical composition comprises **glycophosphopeptical**, in any pharmacologically active form at a concentration of the extract which is effective as a Th1 stimulating agent.
4. comprising the administration to a mammal such as a human in need of such treatment, of an effective dose of **glycophosphopeptical**.
7. The use of the pure seeds of *Nigella sativa* for the preparation of an **asthma** and allergy agent in a concentration which was found to perform substantially the same function in substantially the same way to obtain substantially the same results as with **glycophosphopeptical**.
14. The manufacture of a diagnostic kit to diagnose allergy and **asthma** and to asses the severity Of the disease, using of a quantitative serum interferon concentration measurement.
15. a body immune defensive mechanism is Cell Mediated Immunity as viral respiratory tract infections such as, but not limited to **influenza** and common cold, other viral infections.
18. A method of treatment of viral respiratory tract infections such as, but not limited to **influenza** and common cold, other viral infections comprising the administration to a mammal such as a human in need of such. . .

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